Applicants traverse each of the three rejections of the pending claims under 35 USC 103(a) as being unpatentable over Babbs in view of Douglas, and Gregory in view of Douglas. Applicants submit that the Examiner has failed to establish a prima facie case of obviousness in each instance of rejection.

To better appreciate the prosecution of this application, applicants are providing a historical overview of the previously stated rejections and the amendments and responses thereto. To date, two requests for continued examination have been requested for this application. In the initial Office action of July 17, 2002, Paper No. 7, claims 1-7, 10 and 11 were rejected as being anticipated by Douglas (128). Claims 8 and 9 were rejected as being unpatentable over Douglas in view of Cook (931). In response, independent claim 1 was amended to include that the covering of collagen has an extracellular matrix "that becomes remodeled by host tissue." This feature allows the extracellular matrix of the collagen covering to remodel or grow tissue into the covering of collagen. The collagen-impregnated Dacron graft of Douglas includes a processed bovine collagen that does not have any growth factors or proteins that would facilitate remodeling. Thus, independent claim 1, as amended therein, and claims 2-7, 10 and 11 were distinguished over Douglas. The rejection of dependent claims 8 and 9 were traversed and distinguished over Douglas in view of Cook.

In the final Office action of December 10, 2002, Paper No. 10, claims 1-3 and 7-9 were rejected as being anticipated by Buirge (5,693,085). Claims 4-6 and 10 were rejected as being unpatentable over Buirge in view of Douglas. In response, the subject matter of dependent claim 10 was incorporated into independent claim 1 to distinguish over Buirge. In particular, the collagen covering is a sleeve that initially has a length about equal to twice the length of the stent. The first portion of the sleeve extends along and complements the inside surface of the stent. The second portion of the sleeve is folded back over the proximal end of the stent and then extends along and complements the outside surface of the stent to the distal end thereof. As a result, a construct is formed in which the stent is positioned between two collagen covering layers that extend along and complement both the inside and outside surfaces of the stent

frame. When positioned in the vessel of a patient, the inside and outside of the collagen layers are in direct contact with the innermost surface of the vessel and allow for rapid remodeling and endothelialization of the stent graft covering. With respect to the obviousness rejection of dependent claims 4-6 and 10, applicants distinguished over Douglas in that Douglas does not teach or suggest a covering initially twice the length of the stent that extends along and complements the inside and outside surfaces of the stent. Douglas failed to disclose, teach or even suggest sandwiching graft material that extends along and complements both the inside and outside surfaces of connected stents. Furthermore, Douglas does not teach or suggest the use of a collagen material for the purposes of remodeling.

The Examiner failed to enter applicants' amendment and response to the final Office action, and a first request for continued examination was filed March 10, 2003. In response, claims 1 and 3-7 were rejected as being anticipated by Douglas. Claims 8 and 9 were rejected as being unpatentable over Douglas in view of Babbs. In response, independent claim 1 was amended to include that the covering of collagen has an "isolated" extracellular matrix "layer" that becomes remodeled by host tissue. Again, applicants distinguished over Douglas in that there is absolutely no disclosure, teaching or suggestion of the use of a covering of a collagen, and more importantly, a collagen having an extracellular matrix that becomes remodeled by a host tissue. With respect to dependent claims 8 and 9, the particular orientation of the covering was included in independent claim 1 with the first and second portions being folded over the proximal end of the stent and then extending along and complementing the inside and outside surfaces of the stent to the distal end of the stent. As indicated at that time, this particular configuration recited in independent claim 1, advantageously provided a minimum wall thickness and also advantageously minimized the possibility of blood flowing into the covering of the collagen.

In the final Office action dated November 18, 2003, Paper No. 17, claims 1 and 7-9 were rejected as being anticipated by Babbs. Claims 3-6 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and

any intervening claims. The subject matter of independent claim 1 was included in dependent claim 3, thus simply rewriting claim 3 in independent form. Thus, independent claim 3, as amended therein, and dependent claims 4-6 were in a condition for allowance as indicated by the Examiner. Independent claim 1, was amended to distinguish over Babbs by including that the first and second portions of the sleeve that complement the inside and outside surfaces of the stent are secured to the distal end of the stent. This distinguished over Fig. 2 of Babbs in which the ends of the tubular submucosa tissue are folded over both ends of the stent and adjoined at approximately the mid point on the outside surface. This interconnection of Babbs provides a significant additional thickness of the sleeve, which makes the loading of the stent graft into a delivery catheter much more difficult, and more importantly, significantly reduces the diameter of the stent graft lumen through which blood will flow. As then pointed out, the folded over portions of applicants' sleeve that complements the inside and outside surfaces of the stent significantly and advantageously reduces the overall thickness of the stent graft wall as compared to Babbs, thus maximizing the stent graft lumen and greatly increasing the flow of blood therethrough. Furthermore, attaching the ends of the sleeve at the mid point of the outside surface as depicted in Babbs, greatly increases the possibility of leakage around the stent graft. Thus, contrary to the Examiner's present contention, applicants have previously disclosed that the limitation of complementing inside and outside surface portions attached to the distal end of the stent provides a distinct advantage, is used for a particular purpose and solves an indicated problem. In a recent Fed Circuit decision, the Court indicated that all advantages of a particular invention need not be specifically stated in the application, but only the structure need be disclosed to support such advantages.

The Examiner refused to enter applicants' amendment and response to the previous final Office action. In response, a second request for a continuing examination was filed February 9, 2004, and the previously submitted amendment and response was entered. As a result, the Examiner has now rejected claims 1 and 7-9 as being unpatentable over Babbs. Previously allowable claims 3-6 are

now rejected as being unpatentable over Babbs in view of Douglas, and claims 1 and 3-9 are now rejected as being unpatentable over Gregory in view of Douglas.

With respect to the obviousness rejection of claims 1 and 7-9 over Babbs, applicants traverse this rejection on the basis that the Examiner has again failed to establish a prima facie case of obviousness. Applicants' invention in independent claim 1 includes a covering that extends along and complements both the inside and outside surfaces of the stent to advantageously provide a thin wall construct that maximizes the stent graft lumen and greatly increases the flow of blood therethrough in distinction to the construct of Babbs that reduces the lumen size about the mid point thereof due to the connection of the ends of the collagen material tube on the outside surface of the stent. Furthermore, such a non-complementing construct creates a more turbulent blood flow through the stent graft and significantly increases the possibility of blood leakage around both ends of the stent graft. Such problems were not appreciated by Babbs nor is there any motivation or suggestion in Babbs to modify his construct so that the ends of the sleeve are connected together at the distal end of the stent as in applicants' invention to solve these undesirable problems.

As indicated in MPEP 2143 and 2143.01, the suggestion or motivation to modify the reference must be found in the reference, and the prior art reference must teach or suggest all the claim limitations.

The Examiner contends that it would have been an obvious matter of design choice to a person of ordinary skill in the art to secure the first and second portions to the distal stent. Applicants submit that this contention appears to be merely a matter of substitution of one well known element for another to perform its well known purpose. This is not a statutory basis of rejection, and applicant has clearly disclosed that the limitation of the folded over portions of the sleeve complementing the inside and outside surfaces of the stent is a limitation that provides an advantage, is used for a particular purpose, and solves a stated problem as indicated above. As previously pointed out, securing the ends of the graft to the distal end of the stent with portions of the sleeve extending along and complementing the inside and the outside surfaces of the stent clearly provides

the construct that has better non-turbulent blood flow therethrough. This complementing structure provides a greater and more uniform diameter stent graft lumen over that of Babbs as a result of connecting the inside and outside portions to the distal end. The Babbs construct also facilitates blood leakage around the stent which could easily contribute to increasing the size of the aneurysm, which is trying to be excluded. The purpose of the tube devices may be the same, but clearly applicants' claimed invention is superior in performance due to its structural differences. Furthermore, Babbs does not suggest applicants' modifications and therefore does not teach or suggest applicants' invention as in claims 1 and 7-9. In view thereof, applicants request that the rejection of claims 1 and 7-9 under 35 USC 103(a) as being unpatentable over Babbs, be withdrawn.

With respect to the obviousness rejection of claims 3-6 as being unpatentable over Babbs in view of Douglas, applicants traverse such rejection as again failing to establish a prima facie case of obviousness. First, the Examiner has previously indicated that these claims were allowable after having fully reviewed the same cited references as indicated above. In addition to the arguments previously submitted with respect to Babbs, Douglas fails, as also previously discussed, to teach a structure having a covering of collagen having an isolated extracelluar matrix layer that becomes remodeled by host tissue. Furthermore, the covering has advantageous first and second sleeve portions that extend along and complement both inside and outside the surface of the stent. In addition, Douglas is directed to a bifurcated device in which the stents do not extend along the entire length of the stent graft between folded over portions that complement the inside and outside surfaces of the stents. In addition, there is no motivation or suggestion in either of the two references to combine such to form applicants' claimed invention. In view thereof, applicants submit that a prima facie case of obviousness has not been established and that Babbs and Douglas either singly or in combination do not teach or suggest applicants' claimed invention as detailed above. In view thereof, applicants request that the rejection of claims 3-6 under 35 USC 103(a) as being unpatentable over Babbs in view of Douglas, be withdrawn.

With respect to the rejection of claims 1 and 3-9 as being unpatentable over Gregory in view of Babbs, applicants submit that a prima facie case of obviousness has not been established. Contrary to the Examiner's characterization of Gregory, Gregory does not disclose a stent graft covered by extracellular matrix layer that becomes remodeled by host tissue. As indicated in the discussion of Figs. 8-10, a heterograft is utilized. These heterografts as described in columns 11 and 12, lines 46-6, are formed from a porcine carotid artery in which the digestive vessels appear translucent, pearly white in color, and collapse when removed from water indicating "the absence of collagen and other structurally supportive proteins." This is clearly not a covering of collagen as in applicants' claimed invention that has an isolated extracellular matrix layer that becomes remodeled by host tissue. The reference clearly indicates otherwise, in that the heterograft lacks collagen and other structurally supported proteins, thus making it unable to remodel host tissue. Gregory, like Babbs, discloses in Figs. 8-10 that the heterograft is folded over at both ends of the stent and joined at the middle. This structure, like Babbs, creates a thickened portion at the mid point of the stent graft which reduces the size of the graft lumen and further facilitates an increased potential for leakage at the two ends. The above remarks with respect to Douglas in combination with Babbs are also applicable here. Furthermore, the combination of Gregory and Douglas is less persuasive than that of Babbs and Douglas. In view thereof, applicants submit that there is a lack of suggestion or motivation to combine Gregory and Douglas and even such combination would not teach or suggest applicants' invention in claims 1 and 3-9. In view thereof, applicants request that the rejection of claims 1 and 3-9 under 37 CFR 103(a) as being unpatentable over Gregory in view of Douglas, be withdrawn.

The reexamination and reconsideration of this application is respectfully requested, and it is further requested that the application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment.

Respectfully submitted,

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